

# Exhibit F

[http://www.fda.gov/ora/fiars/ora\\_import\\_ia3310.html](http://www.fda.gov/ora/fiars/ora_import_ia3310.html)

IA #33-10, REVISED 6/22/05 - IMPORT ALERT, #33-10, "DETENTION WITHOUT  
PHYSICAL EXAMINATION OF CANDY DUE TO LEAD"  
ATTACHMENT, REVISED - 4/10/08

NOTE: This import alert is being reissued to accommodate additional candy products subject to detention without physical examination. Asterisks bracket changes (\*\*\*).

TYPE OF ALERT: Detention Without Physical Examination (DWPE)

NOTE: This import alert contains guidance to FDA field personnel only. It does not establish any requirements, or create any rights for, or obligations on, FDA or regulated entities.

PRODUCT : \*\*\* See Attachment \*\*\*

PRODUCT CODE: See attachment

PROBLEM: Excessive levels of lead (HMPB)

PAC FOR  
COLLECTION : 04019A

COUNTRY : See attachment

MANUFACTURER/  
SHIPPER : See attachment

MANUFACTURER/  
SHIPPER I.D.#: See attachment

CHARGE : The article is subject to refusal of admission pursuant to Section 801(a)(3), in that the article appears to bear or contain a poisonous or deleterious substance, lead which may render it injurious to health [Adulteration, Section 402(a)(1)];

and

Its container (paper wrapper) is composed in part of a poisonous or deleterious substance, lead, which may render the contents injurious to health [Adulteration, Section 402(a)(6)];

and/or

It appears to bear or contain a food additive, lead, that is unsafe within the meaning of Section 409 [Adulteration 402(a)(2)(C)]."

RECOMMENDING

OFFICE: LOS-DO (HFR-PA256)  
SAN-DO (HFR-PA152)

REASON FOR

ALERT: From August through October 1994, lollipops from Mexico were detained because of high lead levels. Lead was also found in some of the wrappers. In 1995, FDA initially provided guidance in this import alert that it would consider action against candy products that exceeded 0.5 ppm lead. This guidance allowed for a lead intake from these candies of no more than approximately 10 micrograms of lead per day, based upon an estimated daily candy consumption of 21 grams. More recently, FDA has learned that some candy products have serving sizes substantially larger than 21 grams and FDA believes that children are likely to consume the entire product on one eating occasion. In order to continue to provide the comparable level of protection to children when they eat these larger products, i.e., no more than approximately 10 micrograms per serving, FDA has revised the import alert to indicate that it may also consider action against candy products containing 0.5 ppm or less lead, when the amount of lead per serving is 10 micrograms or more.

In January 1995, SAN-DO analyzed a sample of tamarind candy packaged in green ceramic containers and found approximately 25 parts per million lead.

In July 1996, FDA learned of an investigation conducted by the Orange County, California, Environmental Health Division concerning a child with elevated blood lead levels. The child had consumed Storck brand Eucalyptus Menthol Candy.

A sample of the Storck candy was collected and analyzed by SAN-

DO. The wrapper was found to leach 33,000 ppm lead and the candy was found to contain 0.880 ppm lead. There is evidence that ink from the wrapper is the source of the lead and the amount of lead in the candy was shown to be related to the amount of pigmented ink that transferred to the candy.

The Storck candy was manufactured by Storck Products, Inc., Philippines under license of August Storck KG, 100 Berlin 27, F.R. Germany.

**GUIDANCE:** Districts may detain without physical sampling and analysis, all products identified on the attachment to this alert.

For the individually wrapped candies, both the candy and wrapper should be analyzed for lead in order to overcome the appearance of a violation. Additionally, adequate documentation should be provided showing that the manufacturer has addressed the problem and that the packaging materials (i.e., wrappers including inks) that may contact the food comply with the agency's requirements for contact materials.

In order to consider regulatory action, one of the following conditions must be met:

Analysis of the candy shows potentially harmful levels of lead:

Greater than 0.5 ppm lead, or 0.5 ppm or less lead, and a serving size that would result in a lead intake of 10 micrograms or more per serving. To calculate the amount of lead per serving in micrograms, multiply the lead level in the candy expressed as ppm, by the serving size of the candy expressed in grams. For example, if the lead level in the candy is 0.3 ppm and the serving size is 37 g.  $0.3 \times 37 = 11.1$  micrograms per serving.

Evidence exists that lead has migrated from the wrapper/container to the Candy.

In some cases, there are visual indications of components of the wrapper (ink) migrating to the candy. SAN-DO has documented cases where the lead level is higher in the portion of the candy with a visual indication of migration.

Wrappers should be analyzed using a 24 hour leach at room temperature in a 1N HCL solution. Recommended lead methods of analysis are listed in Compliance Program 7304.019.

Districts should consider that each candy may present a different situation with regard to the potential for regulatory action. For example, the following considerations may be relevant:

is there both an inner and outer wrapper? If there is an inner wrapper, does it act as a barrier to lead migration?

is there ink on any surface that may come in contact with the candy? Is the ink on the inner or outer surface of the wrapper?

The Quick Color Test may be helpful as an indication of whether a packaging surface contains lead. Districts should contact CFSAN/DOE/Imports Branch, Doriliz Mestey, at (301) 436-2772 for questions concerning compliance or criteria for the release of lots.

For questions on issues concerning science, science policy, sample collection, analysis, preparation, or analytical methodology, contact the Division of Field Science, at (301) 827-7605.

#### PRIORITIZATION

GUIDANCE : I

FOI : No purging required.

KEYWORDS : Lead, Candy, Lollipop, Powder Candy, Storck eucalyptus-menthol candy.

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#### DATE LOADED

INTO FIARS : June 22, 2005

ATTACHMENT TO IMPORT ALERT #33-10 - 4/10/08

FIRM

PRODUCT/  
PRODUCT CODE

MANUFACTURER/  
SHIPPER

MEXICO

Candy Pop S.A. De C.V.

Tamarind candy/lollipops

M

Calle 26 No. 1815 Z. Industrial

33S[] []06

Guadalajara, Jalisco, Mexico 8/27/03  
FEI# 3002809020

Carmen Patricia Guzman Lollipop (Sucker) M  
Armenta Av. Plan de Iguala 33C[] []99/33S[] []06  
1339 Col. Lazaro Cardenas 11/8/94  
Mexicali, Baja California,  
Mexico  
FEI #1000256653  
MID #MXCARPAT1339MEX

Fabrica de Dulces Ravi, Pancho's Hot Orange Manufacturer  
S.A. de C.V. Jellies  
Bustamante #801 33L--07  
Colonia Los Nogales  
Monterrey, Nuevo Leon  
Mexico 64260  
FEI #1000439056

Industria Dulcera S.A. de C.V. Chaca Candy M  
Ave Miguel Hidalgo No 13 33J[] []99  
Morelia, Michoacan 33S[] []99  
Mexico 33L[] []05  
FEI #3000214092 04/8 /04

Margarita Guiltron Tamarind candy M  
Ramirez in ceramic jars  
Av. Rio Nilo #2038 33Y[] []99  
Col Lomas 6/5/95  
Guadalajara, Jalisco, Mexico  
FEI #1000333180  
MID #MXMARRAM2GUA

Productos Indy, S.A. De C.V., Hormigas Watermelon M  
Ave. 25 De Mayo 158, flavor Candy  
Bodega A, Col, Fama, 33L[] []02 33E[] []06  
Santa Catarina, Nuevo Leon, 33Y[] []99 33S[] []06  
Mexico 33C[] []99 33S[] []99  
FEI #3000218983 11/19/07

\*\*\*PHILIPPINES\*\*\*

Storck Products, Inc. Eucalyptus-Menthol Candy M

West Capitol Drive 33E[] []06  
 Pasig, Metro Manila 8/21/96  
 Philippines  
 FEI #1000469384  
 MID #PHSTOPROMAN

The firms below are reported to be shippers for this product:

CPMulti-Commodities Corporation

S

17 Clemente St., Bgy. San Agustin  
 Novaliches, Metro Manila  
 Philippines  
 FEI: 146  
 MID: PHCPMCOM17MET

Pacific Isles International Trading, Inc.  
 62-9th Street, New Manila  
 Quezon City, Philippines  
 EFEI: #1000168008  
 MID: PHPACISL62QU

S

Productos Karla SA de CV Vasito Tamarind & Guava  
 Carretera Guadalajara- flavored Soft Candy  
 Saltillo, Km 187 33L[] []99, 33L[] []06,  
 Zacatecas, Tabasco, Mexico 33Y[] []99, 33S[] []99  
 FEI # 1000475421 11/1/06

M